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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/008,955	KLINGEMANN, HANS	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-19,21,24,25,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22,23,26,27,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/22/03* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of Group III in the reply filed on 10/06/06 is acknowledged.

2. Claim 1-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/06.

3. Applicant's election without traverse of treating cancer and unmodified NK-92 cells in the reply filed on 4/27/07 is acknowledged. The unmodified NK-92 cells are structurally and functionally distinct from the modified cells recited in claims 21,24,25,28,29.

4. Claims 21,24,25,28,29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/07.

5. Claims 20,22,23,26,27,30,31 are under consideration.

6. Applicant is required to update the status of all US patent applications in the specification.

7. Regarding the amendment filed 10/22/2003, "Figure 16. Not provided." and "Figure 17. Not provided" need to be deleted from the specification. Then the Figures following 17 should be renumbered in the specification and the submitted drawings. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the aformentioned required renumbering. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

8. The abstract of the disclosure is objected to because according to 37 CFR 1.72 (as per post AIPA changes) the abstract needs to be no more than 150 words. Correction is required. See MPEP 608.01(b).

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 20,22,23,26,27,30,31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-

35,46,48,50,53 of copending Application No. 10/701,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because whilst the two sets of claims differ in scope, both sets of claims encompass in vivo treatment of tumors with NK-92 and cytokine. The NK-92 cells are administered by injection (encompasses intravenous). IL-2 is a cytokine with the property of claim 27. The tumors of claim 23 are art known forms of tumors and are "non-solid". The tumor of claim 32 is solid (only solid tumors could receive intratumor injection).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 20,22,23,26,27,30,31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20,27 are indefinite in the recitation of "NK-92 cell" because it is unclear as to what this term encompasses. The specification, page 5 discloses:
For purposes of this invention and unless indicated otherwise, the term "NK-92" is intended to refer to the original NK-92 cell lines as well as the modified NK-92 cell lines disclosed herein.
It is unclear as to what is encompassed by an "original NK-92 cell line". In addition, the specification, page 13 discloses: *The natural killer cells of this invention are designated NK-92 cells and include* certain treated or transfected modifications of NK-92 cells.
It is unclear as to what "treated modifications of NK-92 cells" means or encompasses.
It is suggested that this issue could be addressed to amend the claims to indicate that the NK-92 cells are ATCC CRL-2407 (as per page 16 of the specification).

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method of claim 31 that recites "non-solid tumor". Regarding applicants comments and the cited passages of the specification, section [0048] discloses:
If the tissue is a part of the lymphatic or immune system, malignant cells may include non-solid tumors of circulating cells.
This passage is the only disclosure of treatment of "non-solid" tumors and is limited to lymphatic or immune system non-solid tumors of circulating cells. The claims encompass treatment of nonimmune/nonlymphoid non-solid tumors wherein there is no disclosure of the scope of said treatment in the specification.

There is no support for the scope of the claimed inventions in the specification as originally filed (eg. the claimed invention constitutes new matter).

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 20,22,23,26,27,30,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. in view of Santoli et al. (US Patent 5,272,082).
Gong et al. teach use NK-92 cells to lyse leukemic tumor cells (see Materials and Methods section and page 654, second column). Gong et al. teach that said cells require IL-2 to function (see page 658, first column). Gong et al. does not in vivo use of NK-92 cells to treat cancer. Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease or in preclinical in vivo studies(see column 10). Santoli et al. teach that said cells are injected iv(see column 10, penultimate paragraph) wherein

injection utilizes a syringe and wherein the injected NK-92 cells would be adjacent to leukemic cells in the blood. Santoli et al. disclose that the cells can be administered with the cytokine IL-2 (see column 7, third paragraph). Santoli et al. teach that said cells can be modified to bind solid tumors (see column 7, last paragraph, continued on next column). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gong et al. teach use of NK-92 cells to lyse tumor cells, while Santoli et al. teach in vivo use of cytotoxic cell lines. One of ordinary skill in the art would have been motivated to do so because Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease or in preclinical in vivo studies(see column 10).

18. The specification refers to the "MG-hIL-2 vector (Figure 7)" on page 47, line 1. Figure 7 in the drawings is not a vector. The only vectors depicted in the drawings are Figure 14 and 15. Figure 14 discloses the MFG-hIL2 vector. Thus, it appears that the "MG-hIL-2 vector (Figure 7)" is actually MFG-hIL-2.
The specification must be corrected so that all references to the figures refer to the appropriate figure.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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